Good Clinical Practices – Consolidated Requirements for Audit Trails and Data Corrections

Requirements	ICH E6 (R3) GCP	ISO 14155 Clin. Inv Med Dev.	EMA/INS/GCP/ 112288/2023	eSource Data	eSys, eRec, eSig in Clin Inv.	PRO Guidance
1. Source records (including audit trails) must follow ALCOA+ principles	2.12.2	7.8.2 a) 10.6 j)	4.1, 4.4, 4.5			
2. Changes should be traceable (to the individual making the change)	2.12.2 12.2.6		4.1, 4.5, 6.2.1	III-A-4 III-B-2	B-Q12	
3. Changes should not obscure original data (or previous entries).	2.12.2 2.12.6 4.2.2(a)(ii)	7.8.2	6.2.1	III-A-4 III-B-2	B-Q12	
4. Changes should be explained if necessary (i.e., the reason for the change)	2.12.2 2.12.6 4.2.2(a)(ii)	7.8.2	6.2.1	III-A-4 III-B-2	B-Q12	
5. Corrections, additions, or deletions to source data are made as appropriate, dated, and explained (if necessary)	3.11.4.5.1(c) 3.16.1(i)		4.4 6.2.1	III-A-4 III-B-2	B-Q12	F
6. Approval of the change is properly documented (including investigator sign-off of data).	3.11.4.5.1		6.3	III-B-2		
7. (Sponsor) Computerized Systems must implement appropriate audit trail functionality requirements	3.16.1(ii)	7.8.3				F
8. Computerized Systems must be assessed for their appropriate “fit for purpose” before use in the clinical trial, including audit trails (i.e., computer validation)	3.16.1(vi) 3.16.1(viii)	7.8.3	4.4 A6.1-2		B-Q8	
9. Sponsor should ensure direct access to source records (including audit trails) is agreed to and provided.	3.16.4		6, 6.1.2, 6.6, A6.8			
10. Relevant metadata, including audit trails, supplies identification of and context to data and should be considered as part of the original record.	4.2.2		4.3 4.4 4.5	III-A-4	B-Q5 Glossary	
11. Audit trails, reports and logs are not disabled (and are not capable of being deactivated by normal users).	4.2.2(b)		6.2.1 A3.3		B-Q12	
12. Audit trails and logs are interpretable and reviewable (and reviewable by monitors)	4.2.2(c)	9.2.4.5				F
13. Date and time of data entries or data transfers or electronic signatures are unambiguous and are automatically captured.	4.2.2(d)		4.5 6.2.1 A5.3.2		D-Q22 E Glossary	F

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14. Determine which audit trails & metadata require review & retention	4.2.2(e)				B-Q12	
15. Planned, risk-based review of audit trails procedures	4.2.3		6.2.2		B-Q8 B-Q12	
16. Data corrections process – corrections are attributable, justified and supported by source records	4.2.4	7.8.2				
17. Audit trail enables reconstruction of event sequence		3.4			B-Q5	
18. Ensure no deletion of entered data (i.e., audit trail) Audit trails must be secure.		7.8.3 f)	4.1			
19. Procedures for data correction process (& training)		J.2	A5.1.1.4		B-Q15	
20. Audits should evaluate data correction process		J.3				
21. Data governance includes control over intentional and unintentional changes to data.			4.1			
22. Data governance systems should create a working environment that encourages reporting of omissions and erroneous results			4.1			
23. Data transfers should be pre-planned, validated and should include audit trails, and should be conducted in such a way that data is continuously accessible.			6.1.2 6.10		D-Q20 D-Q22	F
24. Audit trails should be stored in the computer system.			6.2.1			
25. If audit trails contain information that might unblind the data, then access to blinded users should prevent unblinding.			6.2.1			
26. Decommissioning of systems and databases should allow for the retention of data, including audit trails and metadata, for the required retention period.			6.12		B-Q5	
27. ePRO – if an ePRO system allows for saved data to be changed prior to data submission, the change should be captured in an audit trail.			A5.1.1.2 A5.1.1.4			
28. eCRF – Ability to change eCRF data should be limited to the investigator or delegated clinical study staff				III-A-4		
29. Retention of data, including audit trails, should allow for inspection and the generation of copies for regulatory agencies.					B-Q5 B-Q12	F

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30. For systems with unblinding information, Individual system access information (audit trails) should be retained throughout the study.					B-Q12	
31. Edit checks which prompt a data correction by the user should be audit trailed. NOTE: This practice, if needed, should be performed on a risk basis.					B-Q13	